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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,837	09/26/2003	Menachem Kraus	U014834-5	1334
140	7590	09/28/2004	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,837

Applicant(s)

KRAUS ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☒ Certified copies of the priority documents have been received in Application No. 09/963,427.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. For instance, a recitation of "This application is a division of application no. 09/693,427 filed 10/23/00 issued as U.S. Patent No. 6,629,613." should be included in the first sentence of the specification.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,476,587 (hereinafter referred to as Kuroki et al '587). Kuroki et al '587 teach a method of using a leukocyte filter having a non-woven prefilter and at least one layer of non-cellulosic membrane filter layer having an average pore size ranging from 1 to 5 microns wherein the percentage of the pore volume constituted by pores having specific range of pore cross section diameter are adjusted depending on the use of the leukocyte filter such as leukocyte-separating filter, filter for separating leukocytes and platelets, leukocyte remover and leukocyte/platelet remover for removing leukocytes from blood components such as red blood cells or platelets and/or from whole blood wherein Examples 7-9 in Table 2 shows most frequent pore diameter from 4 microns to 5 microns; furthermore, Kuroki et al '587 teaches that the number of porous

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sheets laminated may appropriately determined by considering the removal rate, filtration time and likelihood of clogging, etc. (see col. 4, line 4 – col. 15, line 26; particularly col. 2, lines 13-19; col. 5, line 60 – col. 6, line 2; col. 6, lines 42-48; col. 8, line 27 – col. 9, line 29; col. 10, line 11 – col. 11, line 5; col. 11, lines 12-58; col. 12, line 37 – col. 15, line 7). Claims 2-21 essentially differ from the method and apparatus of Kuroki et al '587 in reciting claimed limitation of pore surface area/membrane volume ratio or total pore volume of pores having claimed diameters or pore size distribution, etc. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the percentage of the pore volume constituted by pores having specific range of pore cross section diameter in the leukocyte filter of Kuroki et al '587 to arrive at the claimed invention for its use as a leukocyte filter for a specific purpose.

4. Claims 2-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,478,470 (hereinafter referred to as Fukuda et al '470). Fukuda et al '470 teach a method of using a leukocyte filter having a prefilter layer and at least one layer of non-cellulosic membrane filter layer having an average pore diameter of 1 to 25 microns and a total pore volume of 0.4 to 0.95 ml/ml of the porous element wherein the sum of respective pore volumes of pores of the porous element which have a pore diameter of 1 to 30 microns is 90% or more (see abstract) and the porous element has a total pore surface area of 0.5 to 5.7 square meter per ml with the proviso that the sum of respective pore surface areas of pores of the porous element which have a pore diameter of 2 to 30 microns is 50% or more based on the total surface area (see col. 5, lines 47-51) and the sum of respective pore volumes of pores of the porous element which have a pore diameter of less than 2 microns is 8% or less based on the total pore volume (see col. 5, lines 56-59) and the percentage of the pore volume constituted by pores having specific range of pore

cross section diameter are adjusted depending on the use of the leukocyte filter for removing leukocytes from different leukocyte containing suspensions such as a leukocyte-containing red cell product and/or a leukocyte-containing platelet product wherein Examples 1-8 shows average pore diameter from 7.4 microns to 9.2 microns in Table 1-2 and Example 4 shows that the pore volume of pores having diameter exceeding 10 microns is 5% of the total pore volume in Table 2 (see col. 4, line 12 – col. 32, line 3). Claims 2-21 essentially differ from the method and apparatus of Kuroki et al '587 in reciting claimed limitation of pore surface area/membrane volume ratio or total pore volume of pores having claimed diameters or pore size distribution, etc. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the percentage of the pore volume constituted by pores having specific range of pore cross section diameter in the leukocyte filter of Fukuda et al '470 to arrive at the claimed invention for its use as a leukocyte filter for filtering specific leukocyte-containing suspension.

5. Applicant's arguments filed 7/15/04 have been fully considered but they are not persuasive. Applicants argue that both Kuroki and Fukuda teach away from the present invention, as they describe capturing a high percentage (at least 60%) of leukocytes in the prefilter and the present invention describes the prefilter capturing a low percentage (less than 60%) of incoming leukocytes. However, it would have been obvious to one of ordinary skill in the art to use the leukocyte filters of Kuroki and Fukuda to capture as much possible leukocytes in the prefilter as possible. Had the prefilter of Kuroki and Fukuda has capturing of leukocytes less than 60% of leukocytes in blood, it would have been obvious to a person of ordinary skill in

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the art to determine optimum pore size and pore volume of the leukocyte filter to capture the rest of remaining leukocytes passed through the prefilter.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "John Kim", is positioned above the printed name.

John Kim
Primary Examiner
Art Unit 1723

J. Kim
September 23, 2004